

## CLAIMS

1. A high pressure applicator for driving the delivery of a flowable tissue implant material, comprising:

5           a first column having an inner wall, an outer wall, a first open end and a second substantially closed end having an orifice therethrough;

          a second column drivably engageable with said first column, said second column being drivable with respect to said first column to generate a pressure within said first column; and

10           a handle fixedly attached to said first column and radially extending therefrom to provide a user a mechanical advantage upon grasping said handle.

2. The high pressure applicator of claim 1, further comprising at least one sealing element interfacing with said inner wall of said first column, said at least one sealing element enhancing generation of said pressure.

3. The high pressure applicator of claim 1, wherein said second column comprises a wall which is drivably engageable with one of said inner and outer walls.

20           4. The high pressure applicator of claim 1, further comprising a handle integrally formed with or affixed to and extending radially from said second column to provide the user a mechanical advantage upon grasping said handle.

25           5. The high pressure applicator of claim 1, further comprising threading on said outer wall of said first column, wherein said second column is substantially hollow and comprises an open first end, a closed second end and threading on an inner wall thereof, said threading on said second column being engageable with said threading on said first column.

5 6. The high pressure applicator of claim 5; wherein said second column further comprises an extension integrally formed with or affixed to said second column and having an end portion extending from said open end of said second column, said extension adapted to be inserted through said open end of said first column and form a substantial pressure seal with said inner wall.

10 7. The high pressure applicator of claim 6, further comprising at least one sealing element mounted to said end portion of said extension and adapted to form a pressure seal with said inner wall thereby forming a pressure seal between said first and second columns.

15 8. The high pressure applicator of claim 7, wherein said at least one sealing element comprises an O-ring.

20 9. The high pressure applicator of claim 5, further comprising a plunger element adapted to be inserted within said first and second columns, said plunger element having a first end portion and a second end portion.

25 10. The high pressure applicator of claim 9, wherein said first end portion is adapted and configured to closely fit within said inner wall of said first column to form a pressure seal therewith.

11. The high pressure applicator of claim 9, further comprising at least one sealing element mounted to said first end portion and adapted to form a pressure seal between said inner wall and said plunger element.

12. The high pressure applicator of claim 9, further comprising a handle integrally formed with or affixed to and extending radially from said second column to provide the user a mechanical advantage upon grasping said handle.

5           13. The high pressure applicator of claim 11, wherein said at least one sealing element comprises an O-ring.

10           14. The high pressure applicator of claim 11, further comprising at least one frictional element mounted to said second end portion and adapted to form a friction fit with said second column at or near said second closed end.

15           15. The high pressure applicator of claim 3, further comprising threading on at least a portion of said inner wall of said first column, and wherein said wall of said second column is an external wall comprising threading along at least a portion thereof, said threading of said external wall being engageable with said threading on at least a portion of said inner wall.

20           16. The high pressure applicator of claim 15, wherein said threading on said external wall engages with said threading on said inner wall to form a pressure seal therebetween.

25           17. The high pressure applicator of claim 15, further comprising at least one sealing element mounted to an end portion of said second column and adapted to form or enhance a pressure seal with said inner wall thereby forming a pressure seal between said first and second columns.

18. The high pressure applicator of claim 17, wherein said at least one sealing element comprises an O-ring.

19. The high pressure applicator of claim 17, wherein said at least one sealing element comprises a Teflon wrap.

5           20. The high pressure applicator of claim 16, further comprising a handle integrally formed with or affixed to and extending radially from said second column to provide the user a mechanical advantage upon grasping said handle.

10           21. The high pressure applicator of claim 16, wherein said threads cover only a portion of said external wall, with an external wall of an end portion of said second column being relatively smooth.

15           22. The high pressure applicator of claim 21, wherein only a portion of said inner wall comprises threads, the remainder of said inner wall being substantially smooth.

20           23. The high pressure applicator of claim 22, wherein said relatively smooth end portion comprises a reduced diameter section having an outside diameter less than an inside diameter of said threads on said inner wall, and an enlarged section which closely fits with said substantially smooth inner wall to form a pressure seal therewith.

25           24. The high pressure applicator of claim 23, wherein said first column comprises a hinged or removable section adapted to swing open or be removed from said first column to allow insertion of said second column.

25. The high pressure applicator of claim 22, wherein said end portion of said external wall closely fits with said remainder of said inner wall to form a pressure seal therewith.

5           26. The high pressure applicator of claim 25, further comprising at least one sealing element mounted to said end portion of said second column and adapted to enhance said pressure seal.

10           27. The high pressure applicator of claim 25, wherein said at least one sealing element comprises an O-ring.

15           28. The high pressure applicator of claim 1, further comprising a syringe including a barrel portion and a plunger portion, wherein said second column is substantially hollow and comprises an inside wall, an open first end and a closed second end, and wherein said barrel portion is received within said first column and said plunger portion is received within said second column.

20           29. The high pressure applicator of claim 28, further comprising threading on said outer wall of said first column and threading on said inner wall of said second column, said threading on said second column being engageable with said threading on said first column.

25           30. The high pressure applicator of claim 28, further comprising a handle integrally formed with or affixed to and extending radially from said second column to provide the user a mechanical advantage upon grasping said handle.

31. The high pressure applicator of claim 28, wherein an end of said barrel portion abuts against said substantially closed end of said first column and an end of

said plunger portion abuts against said closed end of said second column, wherein driving of said second column with respect to said first column provides a driving force for advancing said plunger portion within said barrel portion.

5           32. The high pressure applicator of claim 29, wherein said barrel portion further comprises a wing or flanged portion adjacent an open end thereof; and  
            said first column comprises a first portion adjacent said open end and a  
            second portion adjacent said substantially closed end and a transitional portion  
10           joining said first and second portions, wherein said first portion has an inside diameter larger than an inside diameter of said second portion, and wherein said transitional portion is adapted to abut against said wing or flanged portion.

            33. The high pressure applicator of claim 1, further comprising a syringe  
15           including a barrel portion and a plunger portion, wherein said syringe is received within said first column.

            34. The high pressure applicator of claim 33, further comprising a handle  
20           integrally formed with or affixed to and extending radially from said second column to provide the user a mechanical advantage upon grasping said handle.

            35. The high pressure applicator of claim 33, further comprising threading on  
25           at least a portion of said inner wall of said first column, and wherein said second column comprises an end adapted to abut an end of said plunger portion and an external wall including threading along at least a portion thereof, said threading of said external wall being engageable with said threading on at least a portion of said inner wall.

36. The high pressure applicator of claim 35, wherein an end of said barrel portion abuts against said substantially closed end of said first column, wherein driving of said second column with respect to said first column provides a driving force for advancing said plunger portion within said barrel portion.

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37. The high pressure applicator of claim 35, wherein said barrel portion further comprises a wing or flanged portion adjacent an open end thereof; and said first column comprises a first portion adjacent said open end and a second portion adjacent said substantially closed end and a transitional portion joining said first and second portions, wherein said first portion has an inside diameter larger than an inside diameter of said second portion, and wherein said transitional portion is adapted to abut against said wing or flanged portion.

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38. The high pressure applicator of claim 1, wherein said applicator is capable of generating pressures of at least about 1000 psi.

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39. The high pressure applicator of claim 38, wherein said applicator is capable of generating pressures of at least 1500 psi.

40. The high pressure applicator of claim 39, wherein said applicator is capable of generating pressures up to about 2000 psi.

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41. The high pressure applicator of claim 40, wherein said applicator is capable of generating pressures up to about 2500 psi.

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42. The high pressure applicator of claim 41, wherein said applicator is capable of generating pressures up to about 3000 psi.

43. A high pressure applicator for driving the delivery of a flowable tissue implant material, comprising:

a first column having an inner wall, an outer wall, a first open end and a second substantially closed end having an orifice therethrough;

a second column adapted to overfit at least a portion of said first column, said second column having an inner wall, an outer wall, an open end and a closed end; and

a plunger element having a first end portion adapted to be inserted within said first column and a second end portion adapted to abut said closed end of said second column.

44. The high pressure applicator of claim 43, further comprising threads on at least a portion of said outer wall of said first column and threads on at least a portion of said inner wall of said second column, said threads on said second column being engageable with said threads on said first column.

45. The high pressure applicator of claim 43, wherein said first end portion is adapted and configured to closely fit within said inner wall of said first column to form a pressure seal therewith.

46. The high pressure applicator of claim 43, further comprising at least one sealing element mounted to said first end portion and adapted to form a pressure seal between said inner wall of said first column and said plunger element.

47. The high pressure applicator of claim 46, wherein said at least one sealing element comprises an O-ring.



48. The high pressure applicator of claim 43, further comprising at least one frictional element mounted to said second end portion and adapted to form a friction fit with said second column at or near said closed end.

49. The high pressure applicator of claim 48, wherein said at least one frictional element comprises an O-ring.

50. The high pressure applicator of claim 43, wherein said second end portion of said plunger element comprises a spherical surface.

51. The high pressure applicator of claim 43, further comprising a handle fixedly attached to said first column and radially extending therefrom to provide a user a mechanical advantage upon grasping said handle.

52. A method of preparing a high pressure applicator for driving the delivery of a flowable tissue implant material for use, said method comprising:

providing an applicator having a first column having an inner wall, an outer wall, a first open end and a second substantially closed end having an orifice therethrough, and a second column drivably engageable with the first column to generate a pressure within the first column;

loading the first column with flowable tissue implant material;  
engaging the second column with the first column to enclose the tissue implant material; and

advancing the second column toward the first column to generate a pressure for driving the flowable tissue material through the orifice.

53. The method of claim 52, wherein the second column includes a plunger adapted to form a pressure seal with the inner wall of the first column and said

engaging the second column with the first column comprises introducing the plunger into the tissue implant material.

5 54. The method of claim 52, wherein said advancing the second column toward the first column to generate a pressure for driving the flowable tissue material through the orifice comprises generating a high pressure of at least 1000 psi.

10 55. The method of claim 52, further comprising connecting a substantially non-compliant tube to the orifice prior to said advancing the second column toward the first column to generate a pressure for driving the flowable tissue material through the orifice.

15 56. The method of claim 52, further comprising connecting a substantially non-compliant tube after said advancing the second column toward the first column to generate a pressure for driving the flowable tissue material through the orifice, thereby purging the orifice prior to connecting the substantially noncompliant tube.

20 57. The method of claim 55, further comprising prefilling the substantially noncompliant tube prior to said connecting to the orifice.

58. The method of claim 57, wherein said prefilling comprises prefilling with saline.

25 59. The method of claim 58, wherein said prefilling comprises prefilling with the tissue implant material.

60. The method of claim 56, further comprising prefilling the substantially noncompliant tube prior to said connecting to the orifice.

61. The method of claim 60, wherein said prefilling comprises prefilling with saline.

5 62. The method of claim 60, wherein said prefilling comprises prefilling with the tissue implant material.

10 63. The method of claim 52, wherein said loading comprises slightly overfilling the first column with the implant material to form a meniscus created by surface tension of the implant material.

15 64. The method of claim 63, wherein said engaging further comprises introducing a plunger element into the implant material and then driving the plunger via said advancing the second column.

20 65. A method of preparing a high pressure applicator for driving the delivery of a flowable tissue implant material for use, said method comprising:

providing an applicator containing at least 5cc of tissue implant material therein; and

25 actuating the applicator to generate an internal pressure of at least 1000 psi which acts as a driving force to force a flow of the implant material from the applicator.

66. The method of claim 65, wherein said actuating generates an internal pressure of at least 1500 psi.

67. The method of claim 66, wherein said actuating generates an internal pressure of at least 2000 psi.

68. The method of claim 67, wherein said actuating generates an internal pressure of at least 2500 psi.

5 69. The method of claim 68, wherein said actuating generates an internal pressure of up to about 3000 psi.

10 70. The method of claim 65 wherein said actuating comprises torquing a first portion of said applicator with respect to a second portion of said applicator to generate said driving force.

71. The method of claim 70, wherein said providing an applicator comprises providing an applicator containing at least 7.5cc of tissue implant material therein.

15 72. The method of claim 71, wherein said providing an applicator comprises providing an applicator containing up to about 9cc of tissue implant material therein.

73. The method of claim 72, wherein said providing an applicator comprises providing an applicator containing up to about 15cc of tissue implant material therein.